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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,544	02/14/2005	Michael W. Dahm	029368.00003	1428
4372	7590	07/05/2007		
ARENT FOX PLLC 1050 CONNECTICUT AVENUE, N.W. SUITE 400 WASHINGTON, DC 20036			EXAMINER GUSSOW, ANNE	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 07/05/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/524,544	Applicant(s) DAHM, MICHAEL W.	
	Examiner Anne M. Gussow	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-13 is/are pending in the application.
- 4a) Of the above claim(s) 8-10 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-7, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/1/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 2 and 3 have been cancelled.
Claims 1, 4, and 11 have been amended.
2. Claims 1, 4-7, and 11-12 are under examination.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on June 1, 2007 contained documents not considered on the initially filed IDS. All documents on the IDS have been considered and an initialed copy of the IDS is included with the mailing of this Office Action.

Objections Withdrawn

4. The objection to the specification is withdrawn in view of applicant's amendments to the specification.

Response to Arguments

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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6. The rejection of claims 1, 4-7, and 11-12 under 35 U.S.C. 112, first paragraph, is maintained.

The response filed June 1, 2007 has been carefully considered but is deemed not to be persuasive. The response states that the art of Traweck, et al. and Slade and Coombs is misplaced because claim 1 is directed to the detection of cytokeratin 1-20 markers of cytokeratin 1-20 expressing tumor cells. In response to this argument, the claims encompass detecting any of cytokeratins 1 to 20 as an epithelial marker on the enriched cell population detected by PCR. The marker detected by PCR in step b is not necessarily the same marker as in the preamble of the claim. Since the disseminated tumor cells can express any of cytokeratins 1 to 20 and the detection of the epithelial marker on the enriched cell population can be any of cytokeratins 1 to 20, the references of Traweck, et al. and Slade and Coombs are relevant. Traweck, et al. teach variability in the detection of cytokeratin 19 in leiomyosarcoma and non-Hodgkin's lymphoma samples, two types of tumor cells. Slade and Coombs teach cytokeratin in insufficiently sensitive and/or specific for detection of solid tumors other than breast cancer. Thus, the art suggests cytokeratin is not a reliable marker of tumor cells and since the claims do not require the cytokeratin marker detected in step b to be the same marker as in the preamble and the claims do not define the specific tumor type, undue experimentation would be necessary to practice the claimed methods with a reasonable expectation of success. As such, the rejection is maintained.

Conclusion

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

June 27, 2007



LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER